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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/636,530 | 08/10/2000 | Thomas L. Cantor | 532212000300 | 7117 |

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EXAMINER

JIANG, DONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 11/06/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,530

Applicant(s)

CANTOR, THOMAS L.

Examiner

Dong Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16 and 22-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment in paper No. 15, filed on 30 July 2003 is acknowledged and entered. Following the amendment, claims 15 and 17-21 are canceled, and claims 14, 16, 22, 26, 30 and 34 are amended.

Currently, claims 14, 16, and 22-38 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 15 and 17-21 are moot as the applicant has canceled the claims.

The enablement rejection of claims 30-33 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

The prior art rejection of claims 14 and 16 under 35 U.S.C. 102(b) as being anticipated by Fukuda (EP 0 528 271 A1) is withdrawn in view of applicant's amendment.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the amended limitation of the peptide fragments of hPTH, wherein the N-terminal starts at any position spanning from position 8 through position 34 of SEQ ID NO:1.

Applicants assert, at page 7 of the response filed on 30 July 2003 (paper No. 15), that the claim is fully supported by the specification, and by virtue of the construction of original claim that clearly encompasses the currently claim PTH antagonist composition. This assertion is not persuasive because nowhere in the specification has position 8 ever been mentioned.

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Changing the claim limitation from "position 2 through position 34" to "position 8 through position 34" has changed the scope of the claim, and such a specific limitation is not supported by the original disclosure. Therefore, the amendment constitutes new matter.

This is a new matter rejection.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16, and 22-38 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 remains indefinite because it is unclear what "*that* has the following ..." in line 7 is intended, does the term "*that*" indicates SEQ ID NO:1 or the portion of PTH? "SEQ ID NO:1 (PTH₁₋₈₄), and has the following ..." is suggested. Claims 22, 26, 30 and 34 are similarly indefinite.

Claim 30 remains further indefinite because the claim does not specify the amount being used in the method for *decreasing* calcium ion concentration in blood in order to achieve said effect set forth in the preamble. A term, such as "an effective amount" is suggested.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Takasu et al. (Endocrinology, 1996, 137(12): 5537-43).

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Takasu discloses a truncated hPTH mutein, hPTH(35-84), and indicates that it significantly inhibited the [35S] hPTH(1-84) binding (the abstract). Although Takasu does not explicitly teach a *pharmaceutical* antagonist of hPTH, it is well known in the art that a purified protein agent is usually used in combination with other agent(s), such as dissolving solutions, and can not be (rather than) used as its crystal form alone. Dissolving solutions, such as water, buffers, or media, would meet the limitation of “pharmaceutical” or “a pharmaceutically acceptable carrier”. As such, Takasu’s hPTH(35-84) anticipates claims 14 and 16.

Claims 22-25 and 30-33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda, EP 0 528 271 A1, for the reasons of record set forth in the last Office Action, paper No. 14, mailed on 26 March 2003, at pages 4-5.

Applicants argument in paper No. 15 has been fully considered, but is not deemed persuasive for reasons below.

At page 10 of the response, the applicant argues that there does not appear to be any indication in Fukuda that PTH peptides with N-terminal deletions are known PTH antagonists, and that recent work by Divieti et al. (Endocrinology, 2002, 143(1): 171-176, provided by applicants) indicates that PTH7-34 (7-84?) does not exhibit PTH antagonistic activity. This argument is not persuasive because Fukuda teaches that “the present invention provides *antagonists* in which several amino acid residues on the N-terminal side of human PTH containing the C-terminal peptide chain are deleted, ...”, which has been reviewed in the last Office Action, at page 4. With respect to the Divieti reference, contrary to applicants interpretation, Divieti teaches that “the present in vitro studies were directed at clarifying whether hPTH(7-84) might act directly on bone to inhibit the action of hPTH(1-84) or hPTH(1-34)” (page 175, the first paragraph of the left column), and concludes “that hPTH-(7-84), ... exerts a direct *antiresorptive effect* on bone that may be partly due to impaired osteoclast differentiation” (the abstract).

At pages 10-11 of the response, the applicant argues repeatedly that Fukuda failed to describe and enable the described “muteins” as PTH antagonists, and the mechanism of action

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thereof as that in the present invention, and fails to indicate which of the numerous potential candidate "PTH muteins" exhibit antagonistic PTH activity as the present claims. This argument is not persuasive because Fukuda, as addressed above, indeed teaches the muteins are PTH antagonists, and can be used for treating hypercalcemia and hyperparathyroidism. With respect to the mechanism of action, and the numerous potential candidates, they are irrelevant because so long as the teachings in disclosure of reference meet the limitations of the present claims, the reference anticipates the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-29 and 34-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda, EP 0 528 271 A1, as applied to claims 14-25 and 30-33 above, and further in view of Kanmera et al., EP 0 451 867, for the reasons of record set forth in the last Office Action, paper No. 14, mailed on 26 March 2003, at pages 5-6.

Applicants argument in paper No. 15 has been fully considered, but is not deemed persuasive for reasons below.

At page 13 of the response, the applicant argues that Kanmera requires actual PTH antagonists as therapeutic agents, the Divieti reference indicates the PTH fragments do not exhibit PTH antagonistic activity as those of currently claimed, and Fukuda does not provide PTH antagonists within the meaning attributed to compositions as provided in Kanmera. This argument is not persuasive because, as clarified above, Fukuda indeed teaches the muteins are PTH antagonists, and Divieti does *not* teach that said PTH fragments do not exhibit PTH antagonistic activity. The Divieti reference merely suggests the possible mechanism through which said PTH fragments exert antagonistic effect as to that of hPTH(1-84) or hPTH(1-34), which is irrelevant to the limitations of the instant claims.

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Conclusion:

No claim is allowed.

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Advisory Information:

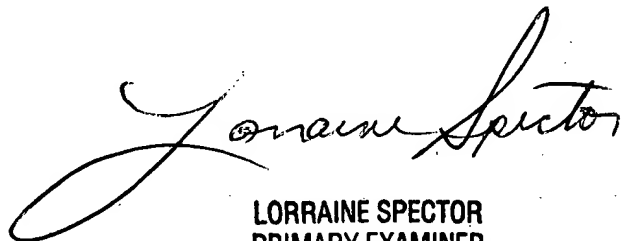
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
10/23/03